

IN THE SPECIFICATION:

Please replace the paragraph at page 13, lines 20-28, with the following:

It is an object of the present invention to provide new and effective methods and compositions for the treatment of various types of disease conditions and defects of the musculoskeletal system and the bone, using genetically engineered muscle-derived cells, e.g., myoblasts and muscle-derived stem cells, (also referred to as MDCs herein) in the cell-mediated delivery of exogenous genes for the expression and production of encoded gene products. The present invention affords a stable gene delivery vehicle to afflicted areas, e.g., the joint (ligament, meniscus, and cartilage), smooth muscle, skeletal muscle and bone, which sustains the production of proteins that ameliorate pathological muscle-related conditions, e.g., musculoskeletal and bone

Please replace the paragraph at page 16, lines 4-19, with the following:

Another object of the present invention is to inject autologous muscle-derived cells (e.g., myoblasts, and muscle-derived stem cells (MDCs)) that have been transfected or transduced with a vector (e.g., viral and non-viral) containing at least one gene encoding a bioactive molecule and, optionally, at least one gene encoding a trophic factor, e.g., a growth factor or a neurotrophic factor, into a muscle tissue, e.g., the urethral wall as an effective treatment for stress urinary incontinence. The muscle-derived cells can be cultured and harvested and can generate sufficient quantities of muscle cells for repeated injections. The present invention is intended to embrace muscle-derived cells which have been genetically engineered to contain genes encoding both a bioactive molecule and a trophic factor. Alternatively, different muscle-derived cells can be engineered to contain either a gene encoding a bioactive molecule or a gene encoding a trophic factor or an immune suppression agent. The different muscle-derived cells can be co-injected or injected at different times, or in combination with other transduced muscle-derived cells, depending upon the type of treatment and therapeutic enhancement desired.

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Please replace the paragraph on page 17, lines 1-11, with the following:

Such muscle-derived cell-mediated gene therapy allows repair and improvement of the urinary sphincter. In accordance with the present invention the treatment comprises a simple needle aspiration to obtain muscle-derived cells, for example, and a brief follow-up treatment to inject cultured and prepared cells into the patient via an outpatient endoscopic procedure. Also according to the present invention, autologous muscle cell injections using myoblasts and muscle-derived stem cells (MDCs) harvested from and cultured for a specific stress incontinence patient can be employed as a nonallergenic agent to bulk up the urethral wall, thereby enhancing coaptation and improving the urinary sphincter muscle. In this aspect of the invention, simple autologous muscle cell transplantation is performed, preferably without an accompanying gene therapy.

Please replace the paragraph at page 23, lines 12-16, with the following:

More particularly, the present invention provides such genetically engineered muscle-derived cells (MDCs), e.g., myoblasts, to improve and expand the treatment of several types of bladder dysfunction including impaired bladder contractility. Also, the present invention provides for the first time the use of skeletal muscle cells for the repair of urinary tract smooth muscle dysfunction.